MEDICATION COVERAGE POLICY

PHARMACY AND THERAPEUTICS ADVISORY COMMITTEE

Health Plan of San Joaquin

POLICY:	ESA/Anemia of Chronic Disease	**P&T DATE:**	9/12/2017
CLASS:	Renal Disease/Genitourinary Disorders	**REVIEW HISTORY:** (MONTH/YEAR)	12/16, 9/15, 9/11, 2/11
LOB:	MCL		

This policy has been developed through review of medical literature, consideration of medical necessity, generally accepted medical practice standards, and approved by the HPSJ Pharmacy and Therapeutic Advisory Committee.

OVERVIEW

Table 1: Available Formulary Agents (*Current as of 8/2017****):***

Class	Generic Name (Brand Name)	Available Strengths	Formulary Status	Notes	Average Cost per 30 days
Iron	Iron Sucrose (Venofer)	100mg/5mL, 50mg/2.5mL IV Solution	PA	Documentation of appropriate diagnosis is required.	--¥
	Ferrous Sulfate (Ferosul, Fer-In-Sol)	325mg IR Tablet, 324mg DR Tablet, 325mg ER Capsule, 15mg/mL Drops, 220mg/5mL Solution, 300mg/5mL Liquid	--		$3.16
Erythropoietin Stimulating Agents (ESA)	Epoetin Alfa (Epogen)	2,000 Unit/mL Injection Solution 3,000 Unit/mL Injection Solution 4,000 Unit/mL Injection Solution 10,000 Unit/mL Injection Solution 20,000 Unit/mL Injection Solution	PA, SP	Procrit is non-formulary. Documentation of appropriate diagnosis is required. Restricted to Diplomat pharmacy.	$724.20
All Iron and ESA products not listed follow HPSJs non-formulary drug policy.					
¥No fills for Venofer during this period (08/2016-07/2017).					

EVALUATION CRITERIA FOR APPROVAL/EXCEPTION CONSIDERATION

Below are the coverage criteria and required information for each agent. These coverage criteria have been reviewed and approved by the HPSJ Pharmacy & Therapeutics (P&T) Advisory Committee. For conditions not covered under this Coverage Policy, HPSJ will make the determination based on Medical Necessity as described in HPSJ Medical Review Guidelines (UM06).

Iron Supplements

Ferrous Sulfate (Ferosul)

- ❒ **Coverage Criteria:** None
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** N/A

Iron Sucrose (Venofer)

- ❒ **Coverage Criteria:**
  Patient is currently on dialysis with recent labs showing TSAT ≤30% and ferritin 500 ng/mL
  OR
  If patient is not on dialysis, documentation that use of less invasive iron supplementation is not sufficient for treatment of the patient's iron deficiency and current labs showing TSAT ≤30% and ferritin ≤500 ng/mL.
- ❒ **Limits:** None
- ❒ **Required Information for Approval:** Documentation that use of less invasive iron supplementation is not sufficient for treatment of the patient's iron deficiency. Iron sucrose (Venofer) is approved 3 months at a time. Submission of TSAT and Ferritin levels with the prior authorization renewal request is required, which shows that TSAT ≤30% and ferritin ≤500 ng/mL.

Erythropoietin Stimulating Agents (ESA)

Epoetin Alfa (Epogen)

- ❒ **Coverage Criteria:** Epogen is indicated when Hemoglobin (Hgb) is < 9 g/dl with TSAT > 20% and serum ferritin > 100 ng/ml at initiation. Hgb should be checked monthly and is not to exceed 11 g/dl. Authorization is for 3 months at a time. For renewal, Hgb must be below 11 g/dL.
- ❒ **Limits:** Restricted to Diplomat Specialty Pharmacy.
- ❒ **Required Information for Approval:** Submit chart notes including the patient's most recent iron studies and CBC.
- ❒ **Additional Notes:**
  - Epogen is approved for 3 months at a time.
  - Submission of Hgb levels with the prior authorization renewal request is required and must not exceed 11g/dL.
  - Procrit is non-formulary.

CLINICAL JUSTIFICATION

Studies have shown that patients who used Epoetin Alfa to target normal levels of Hgb had poor cardiovascular outcomes. These trials showed increases in mortality, nonfatal MI, and hospitalization for CHF. ESA therapy should target a Hemoglobin of less than 11 g/dL. In essence, patients should be treated only to avoid blood transfusion. Iron supplementation is required for most patients with CKD, especially those taking ESAs. Various dosage forms of ferrous sulfate are available on formulary without restriction. Iron sucrose IV solution is available for members unable to take oral iron supplements; prior authorization is required.

ESA Agents

Current clinical practice guidelines for anemia in CKD do not specify which ESA to recommend for a patient.[1] Epogen and Procrit have comparable efficacy and safety profiles. Also, similar efficacy has been shown between Aranesp and Epogen, with no difference in cardiovascular deaths or stroke/MI rates[2].

IV Iron Formulations

Iron supplementation is needed in many patients with anemia, specifically those with CKD. Adult CKD patients on hemodialysis may warrant a trial of IV iron, while adult CKD patients not on hemodialysis may benefit from oral iron supplementation, assuming that TSAT ≤30% and ferritin ≤500 ng/mL[1]. Currently, iron sucrose (Venofer) is the formulary option for patients who require IV therapy. There are many options for IV iron therapy, with most of them showing similar clinical efficacy. There are very few trials available that show head-to-head comparisons between different formulations.

Triage:

1. Duration of Membership
2. Appropriate Diagnosis
3. Current Hemoglobin and Iron studies (TSAT, Ferritin, MCV, Serum Iron)
4. Prescribing Physician Specialty

REFERENCES

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12. INFeD, Package Insert, Watson Pharma, Morristown, NJ, USA, 2009.
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14. Auerbach, M. and Adamson, J. W. (2016), How we diagnose and treat iron deficiency anemia. Am. J. Hematol., 91: 31–38. doi:10.1002/ajh.24201

⌗ REVIEW & EDIT HISTORY

Document Changes	Reference	Date	P&T Chairman
Creation of Policy	Parenteral Iron Therapeutic Class Review 2-15-11.docx	2/2011	Allen Shek, PharmD BCPS
Update to Policy	ESA Criteria Review 9-20-11.docx	9/2011	Allen Shek, PharmD BCPS
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2015-09.docx	9/2015	Jonathan Szkotak, PharmD, BCPCS
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2016-12.docx	12/2016	Johnathan Yeh, PharmD
Update to Policy	HPSJ Coverage Policy - Renal - Anemia 2017-09.docx	09/2017	Johnathan Yeh, PharmD

Note: All changes are approved by the HPSJ P&T Committee before incorporation into the utilization policy